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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/008,957	01/20/1998	ROBERT M. MORIARTY		6842

7590 12/03/2003

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EXAMINER	
BADIO, BARBARA P	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/03/2003

#32

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 32

Application Number: 09/008,957
Filing Date: January 20, 1998
Appellant(s): MORIARTY ET AL.

Harold J. Fassnacht
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the appeal brief filed April 23, 2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

It is noted that claims 2-6 and 10-19 stand rejected. However, applicant has not appeal the rejections of these claims. Therefore, the examiner will address the rejections of claim 1 only.

(4) Status of Amendments after Final

The appellant's statement of the status of amendments after final rejection contained in the brief is corrects.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the rejection of claim 1 is the only one appealed.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,728,643	HOLICK et al.	3-1988
5,254,538	HOLICK et al.	10-1993
5,700,790	GULBRANDSEN et al.	12-1997
5,763,429	BISHOP et al.	6-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holick et al. ('643 and '538), Bishop et al. ('429) and Gulbrandsen et al. ('790).

Each of the above cited reference teaches a generic group of vitamin D derivatives and various uses (see each reference in its entirety). Each reference exemplifies 1α-hydroxyl-vitamin D_4 and/ or 1α-hydroxyl-vitamin D_3 (see especially **'429**, col. 6, line 40; **'790**, col. 2, lines 36 and 42; **'643**, col. 6, line 45; **'538**, col. 10, line 32).

The instant claim differs from the references by reciting a specific species not exemplified by the cited prior art. However, the cited prior art teach equivalence between hydrogen, methyl and/or ethyl at C-24 (see especially, **'429**, col. 5, lines 7-11, 29-58; **'790**, col. 1, line 63 – col. 2, line 42; **'643**, col. 6, lines 1-37; **'538**, col. 4, lines 1-32). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the present invention to select any of the species of the genus taught by the prior art, including 1α-hydroxyl-vitamin D_5 of the instant claim, because the ordinary artisan would have the reasonable expectation that any of the species of the prior art genus would have similar properties and, thus, the same uses as the prior art genus as

a whole. The ordinary artisan would have been motivated to make additional compounds as taught by the cited prior art for use as taught by the prior art.

(11) Response to Argument

Applicant argues that the claimed compound has unexpected properties (i.e., lower calcemic activity) and that no one, including Bishop, anticipated that the claimed compound would have such a favorable property. Applicant also argues that (1) the prior art fail to disclose or render obvious a method of making the claimed compound; (2) none of the named inventors in the cited references, even though the references disclose generic structures that include 1α-hydroxyl-vitamin D_5, knew of the significantly lower calcemic activity of the claimed compound, or else they would have made the compound, or at least tried to make it and (3) there had been a long felt need to develop a vitamin D derivative that has antiproliferative activity but has low calcemic activity. Applicant's arguments were considered but not persuasive for the following reasons.

As stated by applicant, the claimed compound is encompassed by the genus disclosed in all four of the prior art patents. Thus, the compound would have been obvious to one of ordinary skill in the art based on the teachings of the prior art.

Applicant argues that there is no viable synthetic route for making the claimed compound. Applicant also states "appellants did not use known methodology for making 1α-hydroxyl-vitamin D_5 with an ethyl group as the functional side chain. Appellants made 1α-hydroxyl-vitamin D_5 in a totally different way." (see page 10, 2nd paragraph of applicant's brief filed May 23, 2001). The cited passage would contradict applicant's statement that there is no viable synthetic route for making the claimed

compound. Because, applicant is using a different synthetic route for making the claimed compound is not an indication that there is no other route for preparation for the compound. The prior art makes structurally similar compounds, including adjacent homologs of the claimed compound. Thus, the ordinary artisan would be able to make the claimed compound utilizing a process taught by the cited prior art.

Applicant argues that the claimed compound has unexpected properties and points to the lower calcemic action of the claimed compound in comparison to the exemplified prior art compound. Applicant argues that although, Bishop teaches that these compound can be used as antiproliferative agents and cell differentiation agents when exposed to malignant or other hyperproliferative cells without significantly altering calcium metabolism, that the prior art did not know of the significantly lower calcemic activity or they would have made the compound or at least tried to make the compound. Because, the prior art did not make the compound is not relevant. The relevant issue is whether it makes obvious the claimed compound and whether the unexpected properties as argued by applicant is in fact unexpected. The examiner maintains that the data presented by applicant is not unexpected because Bishop teaches that the compounds have a lower tendency or inability to cause the undesired side effects of hypercalcemia and/or hypercalciuria and thus, allows said compounds to be administered as antiproliferative agents etc. without significantly altering calcium metabolism (**'429**, col. 5, line 60 – col. 6, line 13). Therefore, the ordinary artisan would have the reasonable expectation that any of the compounds of the genus taught by the prior art would have these properties. The ordinary artisan would also have the

reasonable expectation that the favorable properties (i.e. lower adverse hypercalcemic and/or hypercalciuria effects) as taught Bishop would vary between compounds of the prior art genus. Therefore, applicant's data is not unexpected because it shows what the ordinary artisan would expect between the prior art compounds.

Finally, applicant argues a long felt need to develop a vitamin D derivative that has antiproliferative activity but has low calcemic activity and reference is made to a number of articles/evidence in support of said need. The examiner notes that said need was considered and identified by Bishop et al. (see Bishop et al., '429, see col. 3, lines 58-67; col. 4, lines 41-58; col. 5, line 60 – col. 6, line 13). Bishop states "[t]he 1α-hydroxyvitamin D compounds of formula (I) of the present invention are those that have effective antiproliferative and cell differentiation activity (i.e., reversal of malignant transformation) particularly with respect to cells of prostatic disease, e.g., prostatic cancer and prostatic hyperplasia, but have a lower tendency or inability to cause the undesired side effects of hypercalcemia and/or hypercalciuria. *In other words,* ***the compounds of formula (I) can be administered at dosages that allow them to act as antiproliferative agents and cell differentiation agents when expose to malignant or other hyperproliferative cells without significantly altering calcium metabolism****. This* ***selectivity*** *and* ***specificity of action*** *makes the 1α-hydroxyvitamin D compounds of formula (I)* ***useful*** *and* ***preferred agents*** *for* ***safely*** *inhibiting hyperproliferation and promoting malignant or hyperplastic cell differentiation. The 1α-hydroxyvitamin D compounds of the present invention, thus, overcome the shortcomings of the known active vitamin D_3 compounds described above and can be*

considered preferred agents for the control and treatment of malignant diseases such as prostate cancer as well as benign prostatic hyperplasia." (see col. 5, line 60 – col. 6, line 13).

In summary, (1) the compound is encompassed by the prior art genus; (2) applicant's declarations do not show any unexpected result because the ordinary artisan would expect differences in the degree to which each compound encompassed by the prior art genus alters calcium metabolism and (3) the prior art teaches the selectivity and specificity of action of the prior art 1α-hydroxyvitamin D compounds, including the claimed compound, and the need for compounds having hyperproliferative property but low calcemic property. Therefore, the art provides the skilled artisan in the art with motivation to made additional compounds as taught by the prior art, including that of the instant claim. The motivation would be based on the desire to obtain the prior art compound(s) having antiproliferative properties and the lowest calcemic action which would overcome the shortcomings of the known active vitamin D_3 compounds.

For the above reasons, it is believed that the rejections should be sustained.

S. QAZI, PH.D
PRIMARY EXAMINER

Respectfully submitted,
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